



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 12-NOV-2014

SUBJECT: **Triclopyr; Triclopyr, Triethylamine Salt (TEA); and Triclopyr, Butoxyethyl Ester (BEE).** Human Health Assessment Scoping Document in Support of Registration Review.

PC Codes: 116001, 116002, 116004

Decision No.: 487442

Petition No.: N/A

Risk Assessment Type: N/A

TXR No.: N/A

MRID No.: N/A

DP Barcode: D417817

Registration No.: N/A

Regulatory Action: Registration Review Scoping Document

Case No.: 2710

CAS Nos.: 57213-69-1, 57213-69-1, 64700-56-7

40 CFR: §180.417

FROM: Jennifer R. Tyler, Chemist
Monique M. Perron, S.D., Toxicologist
Lata Venkateshwara, Environmental Scientist
Risk Assessment Branch 1 (RAB1)
Health Effects Division (HED, 7509P)

THROUGH: Charles W. Smith III, Branch Chief
George F. Kramer, Ph.D., Senior Chemist
RAB1/HED (7509P)

TO: Brittany Pruitt, Chemical Review Manager
Risk Management and Implementation Branch III
Pesticide Re-Evaluation Division (PRD) (7508P)

Attached is HED's human health risk assessment scoping document for triclopyr; triclopyr, triethylamine salt (TEA); and triclopyr, butoxyethyl ester (BEE) to support Registration Review.

11-20-14

Table of Contents

Executive Summary	3
1.0 Introduction.....	5
2.0 Hazard Characterization/Assessment.....	5
3.0 Residue Chemistry	7
4.0 Dietary Exposure	8
5.0 Residential Exposure	9
6.0 Aggregate-Risk Assessment	12
7.0 Occupational Exposure	12
8.0 Public Health and Pesticide Epidemiology Data	13
9.0 Tolerance Assessment and International Harmonization	14
10.0 Environmental Justice	14
11.0 Cumulative.....	14
12.0 Human Studies.....	14
13.0 Risk Assessment Updates, Data Deficiencies, and Label Revisions	15
14.0 References.....	16
Attachment 1: Chemical Identity Table.....	18
Attachment 2: Triclopyr Acute, Subchronic, and Chronic Toxicity Profile.....	19
Attachment 3: Summary of Toxicological Doses and Endpoints for Triclopyr from the Most Recent Human Health Risk Assessment.....	24
Attachment 4: Residential and Occupational Exposure Tables.....	27
Attachment 5: Triclopyr International Residue Limit Status Sheet.....	33

Executive Summary

HED has prepared a scoping document to support Registration Review of triclopyr, triclopyr TEA, and triclopyr BEE. Triclopyr is a selective herbicide belonging to the pyridinoyl acid class of chemicals.

Triclopyr products are formulated as soluble concentrates, emulsifiable concentrates, liquids (pressurized and ready-to-use), granules, wettable powders, and pellets. It is currently registered for use on rice as well as several non-agricultural use sites including rights-of-way, pasture and rangelands, forests, and turf, including home lawns. It is also used to control aquatic weeds growing in lakes, ponds, reservoirs, and wetlands, and to control woody brush and herbaceous weeds in wetlands and on the banks and shores of aquatic sites.

There are currently 142 Section 3 registrations for triclopyr, triclopyr TEA, and triclopyr BEE, as well as 10 active Special Local Needs (SLN) registrations, and 1 Experimental Use Permit (EUP). The most recent quantitative human health risk assessment was performed in 2002 in conjunction with the use of triclopyr on aquatic sites (Memo, W. Donovan *et al.*, 24-JUL-2002; D263770). There are currently pending PRIA actions for 1) removal of grazing restriction for lactating dairy cattle and the establishment of milk and milk fat tolerances; and 2) the registration of triclopyr choline salt for use on all existing registered uses. Risk assessment and characterization of TCP (derived from triclopyr, chlorpyrifos, and chlorpyrifos-methyl) have been assessed in a separate document (Memo, W. Donovan *et al.*, 06-JUN-2002, D283101).

HED has evaluated the status of the human health assessments for triclopyr, triclopyr TEA, and triclopyr BEE to determine whether sufficient data are available and whether any updates are needed to support Registration Review. HED has considered all available data and human health risk assessments for triclopyr with respect to its toxicity, exposure, and usage databases, and the most updated Agency science policy and risk assessment methodologies to determine the scope of work necessary to support Registration Review.

The toxicity database for triclopyr is adequate for risk assessment as specified by the 2007 revised 40 CFR Toxicology Data Requirements, with the exception of a subchronic inhalation study. As a result, an additional 10X database uncertainty factor will be applied for inhalation exposure scenarios. As part of Registration Review, the endpoints, doses, and safety factors used in the most recent human health risk assessment will be re-evaluated according to current HED policy.

The residue chemistry database is adequate to support current Registration Review data requirements. Adequate metabolism, storage stability, magnitude of the residue, and processing data are available to support the registered uses. Adequate methods are available for enforcement of the currently established tolerances. The results of a radiovalidation study to ensure the ability of the gas chromatography with mass-spectrometry detection (GC/MS) method GRM97.02 to recover aged residues should be submitted. In addition, during Registration Review, §180.417 should be updated to include the recommended tolerance expression for fish and shellfish.

The dietary-exposure database is adequate to support current registration requirements. In the most recent risk assessment, acute and chronic dietary exposures (food only) were not of concern to HED [$<100\%$ of the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD)]. However, as part of Registration Review, a revised dietary exposure analysis will be required to reflect the most recent dietary exposure models, inclusion of revised estimated drinking water concentrations (EDWCs) into the analyses, and/or changes to the toxicological points of departure (PODs).

There is sufficient information to assess residential exposure resulting from use of triclopyr on turf, including but not limited to home lawns, golf courses, and athletic field fields, as well as the aquatic use sites such as ponds and lakes. The residential lawn uses include spot and broadcast applications. During Registration Review, all residential handler and post-application dermal and inhalation exposure scenarios need to be assessed using HED's 2012 Residential standard operating procedures (SOPs) along with policy changes for body weights and current toxicological endpoints. The need for spray drift and volatilization risk assessment for triclopyr will also be examined during Registration Review.

Based on current HED policy, a turf transferrable residue (TTR) study is required for triclopyr to support the use on home lawns, golf courses, and athletic fields. An updated residential exposure assessment will be required under registration review that incorporates the findings of the TTR study and the most updated residential SOPs to address post-application exposure to adults and children high contact lawn activities on commercially treated turf.

There is sufficient information available to assess aggregate exposure. A new aggregate risk assessment will be required during Registration Review to incorporate revised dietary exposure analyses and revised residential exposure assessments.

There is sufficient information available to assess occupational handler exposure associated with agricultural, commercial, and aquatic uses of triclopyr for Registration Review. Several occupational handler scenarios need to be assessed, which have not been assessed previously, or need to be reassessed based on higher application rates, area treated, or revised SOPs. In addition, post-application dermal exposure will need to be assessed for those use sites and activities not assessed previously. In addition, the need for a quantitative occupational post-application inhalation exposure assessment will be considered for triclopyr during Registration Review.

The following data deficiencies were identified for triclopyr:

Toxicology

- Subchronic Inhalation Toxicity Study (870.3465)

Residue Chemistry

- The results of a radiovalidation study to ensure the ability of the gas chromatography with mass selective detection (GC/MSD) method GRM97.02 to recover aged residues [860.1340(c)(3)].

Occupational/Residential Exposure

Chemical-specific TTR study (875.2100)

In addition, EPA anticipates conducting the following risk assessment updates during Registration Review:

Toxicology

- Reevaluation of toxicity endpoint/dose selection, along with the Food Quality Protection Act (FQPA) Safety Factor (SF) based on current HED policy.

Residue Chemistry

- Updated §180.417 to include the recommended tolerance expression for fish and shellfish.

Dietary Exposure

- Revised dietary exposure analysis to reflect the most recent dietary exposure models, potential revised EDWCs, and/or changes to the toxicological PODs.

Aggregate Exposure

- New aggregate risk assessment to incorporate revised dietary exposure analyses and/or revised residential exposure assessments.

Occupational/Residential Exposure

- Revised occupational and residential exposure assessments to cover all registered uses and formulations, accounting for maximum application rates, and/or policy changes will be required during Registration Review.
- Examination of the need for spray drift and volatilization risk assessments for triclopyr.

1.0 Introduction

Triclopyr, triclopyr TEA, and triclopyr BEE products are used as selective herbicides to control broad leaf weeds. Triclopyr products are registered for use on rice as well as a variety of non-agricultural sites including rights of way, pasture and rangelands, forests, rice, and turf (including home lawns), golf courses, cemeteries, parks, lakes, bayous, ponds, reservoirs, marshes, roadsides, fence rows, canals, ditch banks, athletic fields, storage yards, industrial sites, trails, patios, camp areas, homes and cabins (outdoor), and christmas tree plantings. Triclopyr products are formulated as soluble concentrates, emulsifiable concentrates, liquids (pressurized and ready-to-use), granules, wettable powders, and pellets. There are currently ten active SLNs and one EUP for triclopyr, triclopyr TEA, and triclopyr BEE for various use sites. The most recent quantitative human health risk assessment was performed in 2002 for the use of triclopyr on aquatic sites (Memo, W. Donovan *et al.*, 24-JUL-2002; D263770). There are currently pending PRIA actions for 1) removal of grazing restriction for lactating dairy cattle and the establishment of milk and milk fat tolerances; and 2) the registration of triclopyr choline salt for use on all existing registered uses.

2.0 Hazard Characterization/Assessment

The bioequivalency of the three chemical forms of triclopyr (acid, triethylamine salt, and butoxyethyl ester) has been addressed through a variety of special studies with the salt and ester forms, including data on comparative disposition, plasma half-life, tissue distribution, and hydrolytic cleavage. These studies were found to adequately address the issue of bioequivalency. Therefore, studies conducted with any one form of triclopyr have been used to support the toxicology database as a whole.

In a rat metabolism study with ^{14}C -triclopyr acid, absorption, distribution, metabolism, and excretion were assessed following single oral doses of 3 mg/kg or 60 mg/kg, repeated doses of 3 mg/kg, and an intravenous dose at 3 mg/kg. Regardless of dose level or route of administration, triclopyr was well absorbed with peak plasma levels reached within 3-4 hours. Radioactivity in the tissues at 72 hours was minimal ($<0.54\%$). At the low dose, $>90\%$ of the radioactivity was excreted within 24 hours primarily via the urine. The high dose yielded similar overall results except that urinary elimination was decreased between 0-12 hours due to saturation of renal excretion mechanisms. Unmetabolized parent represented $>90\%$ of the urinary radioactivity.

Triclopyr has been classified as having low acute toxicity via the oral, dermal and inhalation routes (Toxicity Category III-IV). The salt form was found to be corrosive to the eye, while the ester form was only minimally irritating. Both the salt and ester forms of triclopyr were found to be dermal sensitizers, but not a dermal irritant.

In subchronic oral studies in rats, degeneration of the proximal tubule of the kidney was the primary effect observed with the acid and ester forms of triclopyr at 20 mg/kg/day and 28 mg/kg/day, respectively. This effect was also observed in rats from chronic exposure to triclopyr in parental animals in the two-generation reproduction toxicity study at 25 mg/kg/day and in the rat combined chronic/carcinogenicity study at 36 mg/kg/day.

In a 228-day oral toxicity study in dogs, increased liver enzymes, increased liver weights, and liver histopathology were observed in both sexes at 20 mg/kg/day [no-observed-adverse-effect level (NOAEL) = 10 mg/kg/day]. Changes in hematological parameters (decreased packed-cell volume, decreased hemoglobin, and decreased red blood cell count) were also observed at this dose. No adverse effects were seen in a one-year dietary study in dogs.

Offspring and developmental effects occurred in the presence of maternal and parental toxicity. In the two-generation reproduction study with triclopyr acid, rare malformations, including exencephaly (brain protrudes outside of the skull) and ablepharia (absence of eyelids), were seen in rat pups at the mid- and high-doses (25 mg/kg/day and 250 mg/kg/day, respectively). These malformations were considered, using a weight-of-evidence (WOE) approach, to be evidence of qualitative increased susceptibility by the Hazard Identification Assessment Review Committee (HIARC) Developmental/Reproductive Toxicity Peer Review. A concern for qualitative susceptibility also exists in the rat developmental toxicity study with triclopyr acid, although the evidence was not as conclusive as in the rat reproduction toxicity study. Cleft palate, brachycephaly, and delayed ossification occurred at the highest dose tested (200 mg/kg/day), while the NOAEL for maternal toxicity was not established since clinical signs of severe toxicity due to the bolus administration of a low pH compound were seen at the lowest dose tested (50 mg/kg/day). There were no other concerns for susceptibility identified in the other developmental studies where developmental and maternal effects were seen at 100 mg/kg/day and 300 mg/kg/day in the rabbit and rat, respectively.

Triclopyr has been classified as a “Group D Chemical – unable to be classified as to human carcinogenicity.” This is based on marginal evidence of mammary tumors in female rats and

mice and benign adrenal pheochromocytomas in male rats. There was no evidence of mutagenicity in a full battery of studies for triclopyr.

Since the most recent risk assessment for triclopyr, acceptable subchronic neurotoxicity (MRID 49306303) and immunotoxicity (MRID 49433001) studies have been submitted and show no evidence of neurotoxicity or immunotoxicity, respectively. Waivers have also been submitted by the registrant for the acute neurotoxicity (ACN) and inhalation studies. The HED Hazard and Science Policy Council (HASPOC) discussed the need for these studies using a WOE approach (J. Leshin; TXR# 0057009). HASPOC concluded that the ACN is not required at this time. The subchronic inhalation study is required at this time, and an additional 10X database uncertainty factor will be applied for assessment of inhalation exposure scenarios. The endpoints and points of departure from the most recent human health risk assessment for triclopyr (W. Donovan; 24-JUL-2002; D263770) can be found in Attachment 3.

Conclusions: The toxicity database for triclopyr is adequate for risk assessment as specified by the 2007 revised 40 CFR Toxicology Data Requirements, with the exception of a subchronic inhalation study. As a result, an additional 10X database uncertainty factor will be applied for assessment of inhalation exposure scenarios. As part of Registration Review, the endpoints, doses, and safety factors used in the most recent risk assessment will be re-evaluated according to current HED policy.

3.0 Residue Chemistry

Currently, permanent tolerances are established for the combined residues of triclopyr *per se*, as a result of the application/use of butoxyethyl ester of triclopyr and triethylamine salt of triclopyr, in or on eggs; fish; grass forage and hay; milk; poultry fat, meat, and meat byproducts, except kidney; rice, grain and straw; and shellfish [40 CFR §180.417 (a)(1)]. In addition, permanent tolerances are established for residues of triclopyr acetic acid and its metabolite TCP, as a result of the application/use of butoxyethyl ester of triclopyr and triethylamine salt of triclopyr, in or on the meat, fat, and meat byproducts of cattle goats, hogs, horses, and sheep [40 CFR §180.417 (a)(2)]. There are currently no established Section 18 Emergency Exemption tolerances or tolerances for indirect/ inadvertent residues in rotational crops.

The qualitative nature of the residue in rice, grass, fish, shellfish, and livestock is adequately understood based on the available metabolism studies. The residues of concern are as follows (Memos, W. Smith, 15-JUL-1996; W. Donovan, 27-APR-2001, D274243): triclopyr *per se* in grass, rice, milk, poultry, and eggs; triclopyr and TCP in meat, meat byproducts and drinking water; and triclopyr, TCP, and 2-methoxy-3,5,6-trichloropyridine (TMP) in fish and shellfish. It should be noted that §180.417(a)(1) lists the tolerance expression for fish and shellfish as triclopyr *per se*. §180.417 should be updated to include the recommended tolerance expression for fish and shellfish.

Adequate methods are available for tolerance enforcement and data collection. Two GC methods (Methods I and II) with electron-capture detection (GC/ECD) are available for the determination of triclopyr residues of concern. Method I (Dow Chemical Co. Method ACR 77.4) separately determines residues of triclopyr, 3,5,6-trichloro-2-pyridinol, and 2-methoxy-

3,5,6-trichloropyridine and has successfully undergone an Agency method validation using grass commodities. Method II (Dow Chemical Co. Method ACR 77.2) determines residues of triclopyr *per se* in milk, cream, and tissues, and has detection limits of 0.05-0.1 ppm. Another GC/ECD method is available for the enforcement of tolerances of 3,5,6-trichloro-2-pyridinol in meat; the method is listed in PAM Volume II as Method V under chlorpyrifos. GC/MS method GRM97.02 is available for the determination of triclopyr, TCP, and TMP in fish and shellfish. In the 2002 human health risk assessment, HED recommended the petitioner submit the results of a radiovalidation study to ensure the ability of the GC/MS method GRM97.02 to recover aged residues. To HED knowledge, these data have not been submitted.

The Food and Drug Administration (FDA) PESTDATA database dated 1/94 (PAM Vol. I, Appendix I) indicates that triclopyr is completely recovered (>80%) using multiresidue method PAM Vol. I Section 402. Data pertaining to multiresidue methods testing of triclopyr and its metabolites through Protocols B, C, D, and E have been submitted and forwarded to FDA.

Adequate field trial data are available to support the use of triclopyr on the registered crops. An adequate number of trials were conducted in the appropriate geographical regions using the appropriate formulation applied at the maximum use rate. These studies are also supported by adequate storage stability data and processing data.

Conclusions: The residue chemistry database is adequate to support current Registration Review data requirements. Adequate metabolism, storage stability, magnitude of the residue, and processing data are available to support the registered uses. Adequate methods are available for enforcement of the currently established tolerances. The results of a radiovalidation study to ensure the ability of the GC/MS method GRM97.02 to recover aged residues should be submitted. In addition, PRD should ensure that §180.417 is updated to include the recommended tolerance expression for fish and shellfish.

4.0 Dietary Exposure

The most recent acute and chronic dietary exposure analyses (food only), which considered all currently registered uses, was conducted by HED in 2002 (Memo, W. Donovan, 16-APR-2002; D275030). The assessment was conducted using the Dietary Exposure Evaluation Model (DEEM, Version 7.75), which utilized consumption data from the USDA 1989-92 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). For acute and chronic dietary risk estimates, HED's level of concern (LOC) is >100% aPAD and cPAD, respectively. The acute and chronic dietary exposure analyses were partially refined, incorporating anticipated residues (ARs), default processing factors, and percent crop treated (%CT) information for agricultural crops. ARs were calculated for rice, shellfish, fish, and livestock commodities using data from field trial and ruminant feeding studies. The %CT information was provided by the Biological and Economical Analysis Division (BEAD) (Memo, F. Hernandez, 20-MAR-2001). BEAD has provided an updated Screening Level Usage Analysis (SLUA) Report (19-APR-2013). The acute dietary food exposure estimate was less than HED's LOC (<100% of the aPAD) at the 99.9th percentile of exposure for the general U.S. population and all population subgroups (the most highly exposed population subgroup was females 13-50 years old at 11% of the aPAD). The chronic dietary food exposure estimate was less than HED's LOC (<100% cPAD) for the

general U.S. population and all population subgroups (the most highly exposed population subgroup was children 1-6 years old at 0.2% of the cPAD).

Drinking Water: In conjunction with the most recent human health risk assessment, EFED provided a drinking water assessment of triclopyr for wetland use, aquatic use, and for terrestrial uses (Memos, Davy, Mahoney & Syslo, 15-MAR-2001, D263769; M. Mahoney, 06-MAR-2002, D281429; and M. Mahoney & I. Kennedy, 17-JUN-2002, D283715). The acute and chronic triclopyr estimated environmental concentrations (EECs) for surface water are 1049 and 390 ppb, respectively. For all uses, the surface water EEC exceeded the ground water EEC and was recommended for use in the risk assessment. Drinking water estimates were not incorporated directly in the dietary assessment. HED calculated drinking water levels of comparison (DWLOCs), which is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses (see Section 6.0).

Conclusions: The dietary-exposure database is adequate to support current registration requirements. In the most recent risk assessment, acute and chronic dietary (food only) exposures were not of concern to HED (<100% of the aPAD and cPAD). However, as part of Registration Review, a revised dietary exposure analysis will be required to reflect the most recent dietary exposure models, inclusion of revised EDWCs into the analyses, and/or changes to the toxicological PODs.

5.0 Residential Exposure

There is sufficient information to assess residential exposure resulting from use of triclopyr on turf, including but not limited to home lawns, golf courses, and athletic field, and aquatic use sites such as ponds and lakes. The residential lawn uses include spot and broadcast applications. Due to this use profile, adult residential homeowners may experience exposure to triclopyr during application of the chemical (i.e., residential handler exposures). Adults and children may experience exposure to triclopyr when contacting triclopyr-treated areas (i.e., residential post-application exposure). There are hundreds of products that contain triclopyr, triclopyr salts, and triclopyr esters. HED focused on a subset of these labels that covered a majority of the uses in order to identify use sites and application rates. A summary of residential uses is listed in Attachment 4 (Table A10).

Residential Handlers: HED has previously assessed the use of triclopyr for residential use including lawn spot and broadcast applications (Memo, J. Swackhammer, 22-JUL-2002; D269448). The products registered for residential spot treatment can be applied by homeowners; therefore, short-term residential handler dermal and inhalation exposure is expected. The 2002 residential handler assessment was based primarily on the following data sources: the 1997 Residential SOPs and the Pesticide Handler Exposure Database (PHED) unit exposures. Residential handler exposure was assessed at a rate of 0.56 lb ae/A for granular applications and 0.00006 lb ae/ft² for spray applications. The results of the 2002 residential handler exposure and risk assessment indicate that combined risks do not exceed HED's LOC (i.e., margins of exposure (MOEs) greater than 100) for any of the use scenarios (Attachment 3, Table All).

A review of the registered labels indicates that higher application rates are registered for use in residential settings. Therefore, during registration review, the residential handler assessment for these scenarios will need to be revised based on these higher application rates. In addition, all residential handler exposure scenarios need to be assessed during registration review using HED's 2012 Residential SOPs along with policy changes for body weights and current toxicological endpoints.

Residential Post-Application: Triclopyr can be applied in residential settings including residential lawns, golf courses, and aquatic use sites, such as ponds and lakes; therefore, residential post-application exposure is expected. In the 2002 memo, adult short-term dermal post application exposures, and short-term toddler dermal and incidental oral post-application exposures were assessed from the use on turf (Memo, J. Swackhammer, 22-JUL-2002; D269448). Triclopyr is also registered for use at recreational sites, including golf courses. Adult and child golfers are anticipated to have short-term post-application dermal exposures. HED also evaluated child and adult swimmers for short-term post-application incidental ingestion and dermal exposures resulting from the aquatic uses of triclopyr. Three field dissipation studies using Garlon® (MRID 4456102, 44456103, and 44456104) in lake and pond settings were reviewed and used for the post-application swimmer assessment. The results of the 2002 residential post-application exposure and risk assessments indicate that combined risks do not exceed HED's LOC (MOEs greater than 100) for any of the exposure scenarios (see Attachment 4, Tables A12-A15). During registration review, all residential post-application exposure scenarios, including uses in golf courses and aquatic sites, will need to be assessed using HED's 2012 Residential SOPs along with policy changes for body weights and current toxicological endpoints.

In accordance with 40 CFR158, TTR data are required for all occupational (e.g., sod farms, golf courses, parks, and recreational areas) or residential turf uses that could result in post-application exposure to turf. In the absence of chemical-specific TTR data, EPA uses default values. The *2012 Standard Operating Procedures for Residential Pesticide Exposure Assessment* includes an analysis of all TTR data, available at the time, which resulted in the selection of revised liquid and granular default values for the fraction of the application rate available for transfer after a turf application (F_{AR}). These values are based on an analysis of 59 TTR studies performed with the Modified California Roller Method (36 studies using liquids, 11 studies using wettable powders/water dispersible granules, and 12 studies using granules). The liquid results (N=131) indicate a range of F_{AR} values from 0.0005% to 6.1% and the granular results (N=37) indicate a range of 0.00064% to 0.69%. In both the liquid and granular data, a large range of transferability is observed and this variability can potentially be attributable to many factors such as active ingredient; formulation; field conditions in the studies; weather conditions (e.g., humidity); or many other difficult to quantify factors. Although witnessed across multiple chemicals, this range in F_{AR} values is not expected when considering TTR data for a single chemical. EPA selected 1% and 0.2% as the reasonable, high-end default values for liquid and granular products, respectively. Because TTR data are not available for triclopyr, EPA is using the default value of 1%. Although there may be a small degree of uncertainty in the use of the default TTR value for triclopyr (i.e., there is a small chance that the F_{AR} value may exceed the applicable default value), it is likely that the health-protective aspects of EPA's residential post-application turf assessment methodology will more than compensate for this potential

uncertainty. For example, when assessing residential post-application turf exposure, EPA assumes the following: exposures occur to zero-day (i.e., day of application) residues every day of the assessed exposure duration (i.e., EPA assumes that no dissipation or degradation occurs, it doesn't rain, the grass is not mowed, etc); individuals perform the same post-application activities performed in the turf transfer coefficient study day after day (e.g., tumbling, playing on turf with toys, etc.); and individuals engage in these post-application activities for a high-end amount of time every day (represented by data reflecting time children spend outdoors and not specifically engaged in activities on turf). In actuality, residues will dissipate to some degree depending on the chemical; children do not play on turf every day; children do not spend all of their outdoor time on turf; and high-end levels of activity will not occur every day even if children are playing on treated turf.

Given the conservatisms discussed above and the potential compounding nature of these conservatisms, EPA is able to rely upon the calculated exposure estimates with confidence that exposure is not being underestimated. Since the estimated residential turf post-application exposure using default TTR values for triclopyr is not minimal in comparison to the level of concern (i.e., the calculated MOE is not greater than 10 times higher than the level of concern, MOE = 320 compared to the LOC of 100; EPA is requiring the 40 CFR TTR data.

Spray Drift/Bystander Exposure: Residential bystander exposures resulting from off-site transport (e.g., spray drift or volatilization) may occur as a result of applications of triclopyr. The potential for spray drift will be quantitatively evaluated for each pesticide during the Registration Review process that ensures that all uses for that pesticide will be considered concurrently. The approach is outlined in the revised (2012) SOPs for Residential Risk Assessment – Residential Exposure Assessment Standard Operating Procedures Addenda 1: Consideration of Spray Drift (<http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2013-0676>). This document outlines the quantification of indirect non-occupational exposure to drift.

In terms of volatilization, the agency has developed a Volatilization Screening Tool and a subsequent Volatilization Screening Analysis (<http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0219>). During Registration Review, the agency will utilize this analysis to determine if data (i.e., flux studies, route-specific inhalation toxicological studies) or further analysis is required for specific chemicals.

Conclusions: There is sufficient information to assess residential exposure resulting from use of triclopyr on turf, including but not limited to home lawns, golf courses, and athletic field fields, as well as the aquatic use sites such as ponds and lakes. The residential lawn uses include spot and broadcast applications. During Registration Review, all residential handler dermal and inhalation exposure scenarios need to be assessed using HED's 2012 Residential SOPs along with policy changes for body weights and current toxicological endpoints. The need for spray drift and volatilization risk assessment for triclopyr will also be examined during Registration Review

6.0 Aggregate-Risk Assessment

The most recent aggregate-risk assessment was performed in conjunction with the 2002 HED human health risk assessment (Memo, W. Donovan *et al.*, 24-JUL-2002; D263770). Human health risk assessments were conducted for the following exposure scenarios: acute and chronic aggregate exposure (food only) and short- and intermediate-term aggregate exposure (background chronic dietary exposure (food only) and short- and intermediate-term oral exposures from residential uses). Other scenarios were not calculated since triclopyr has not been classified as a carcinogen, and long-term residential exposures are not expected. All aggregate risks for triclopyr were below HED's LOC (MOEs greater than 100). Since drinking water was not incorporated into the dietary exposure assessment, DWLOCs were calculated. For surface and ground water, the EECs of triclopyr were less than HED's DWLOCs for triclopyr in drinking water for all exposure scenarios. Therefore, HED concluded with reasonable certainty that residues of triclopyr in drinking water would not contribute significantly to the acute, chronic, and short-term aggregate human health risk.

Conclusions: There is sufficient information available to assess aggregate exposure. A new aggregate risk assessment may be required during Registration Review to incorporate revised dietary exposure analyses and/or revised residential exposure assessments.

7.0 Occupational Exposure

Triclopyr containing herbicides are used for weed control in rangeland, pastures, rice, and other non-crop areas. As stated above, there are hundreds of products that contain triclopyr, salts, and esters. HED focused on a subset of these labels that covered a majority of the uses. Based on these uses, there is a potential for exposure to triclopyr in occupational scenarios from handling triclopyr products during the application process (i.e., mixer/loaders, applicators, flaggers, and mixer/loader/applicators); and a potential for post-application worker exposure from entering into areas previously treated with triclopyr. A summary of occupational uses is listed in Attachment 4 as Table A16.

Occupational Handlers: According to the April 22, 1997 Reregistration Eligibility Decision Document for Triclopyr, it appears that rice, pasture and rangeland handler exposures were evaluated but there were no toxicological dermal and inhalation endpoints at that time; therefore, a quantitative assessment was not conducted at that time. Quantitative occupational handler assessment has only been conducted for the aquatic weed uses of triclopyr (Attachment 4, Table A16).

Occupational handler assessments have not been performed for the following use scenarios:

- Rice crop use scenarios (aerial and ground).
- Pasture and rangeland use scenarios (aerial, ground, sprayer, and backpack).

These scenarios will need to be assessed during registration review.

Occupational Post-Application: The Agency has determined that there is the potential for occupational post-application exposures to individuals entering areas treated with triclopyr. In 2002, a post-application assessment was performed for personnel entering wetland sites

following applications could potentially have short-term dermal exposures (Attachment 4, Table A17). According to the April 22, 1997 RED for Triclopyr, rice, pasture and rangeland postapplication exposures were evaluated but there were no toxicological dermal and inhalation endpoints at that time; therefore, a quantitative post-application assessment was not conducted. In addition, since that time, HED reviewed *A Dissipation of Dislodgeable Foliar Residues of triclopyr triethylamine from Treated Rice* D28623, 04/14/2003, but these chemical-specific data have not been used in previous assessments.

Updated occupational handler exposure assessments will be required under Registration Review based upon revisions to the Agency's scenario-specific surrogate handler exposure data (<http://www.epa.gov/pesticides/science/handler-exposure-table.pdf>). Updated occupational post-application exposure assessments will also be required under Registration Review based upon revisions to the dermal transfer coefficients from the Science Advisory Council for Exposure Policy Number 3 (http://www.epa.gov/pesticides/science/exposac_policy3.pdf). Revised occupational handler and post-application assessments may also be needed if toxicological endpoints change or other new data are received by the Agency that impact exposure estimates.

Based on the Agency's current practices, a quantitative occupational post-application inhalation exposure assessment has not been performed for triclopyr. However, there are multiple potential sources of post-application inhalation exposure to individuals performing post-application activities in previously treated fields. These potential sources include volatilization of pesticides and resuspension of dusts and/or particulates that contain pesticides. In terms of volatilization, the agency has developed a Volatilization Screening Tool and a subsequent Volatilization Screening Analysis (<http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0219>). During Registration Review, the agency will utilize this analysis to determine if data (i.e., flux studies, route-specific inhalation toxicological studies) or further analysis is required for specific chemicals.

Conclusions: There is sufficient information available to assess occupational exposure for registration review. During registration review, occupational handler dermal and inhalation exposure assessments need to be performed for the scenarios that have not been previously assessed. Also post application dermal exposure will need to be reassessed based on higher application rates, area treated, or revised SOPs. In addition, the need for a quantitative occupational post-application dermal and inhalation exposure assessment will be considered for triclopyr during Registration Review.

8.0 Public Health and Pesticide Epidemiology Data

A summary report listing incidents for triclopyr reported to the OPP Incident Data System (IDS) has been provided for the docket (Memo, E. Evans and S. Recore, 29-APR-2014; D419814). The report represents incidents occurring in the U.S. from 2000 to the present for triclopyr. There is a moderately high absolute number of incidents reported involving triclopyr in IDS. Although the vast majority of these incidents were of low severity, some high-severity outcomes are reported in the IDS database. Based on the IDS reports, incidents usually involved homeowners who were mixing/loading and/or applying, and the symptoms most often reported

were dermal and neurological. HED will re-evaluate the need for a new incident report during Registration Review.

9.0 Tolerance Assessment and International Harmonization

U.S. permanent tolerances (listed in 40 CFR 180.417) are summarized in Attachment 5. All U.S. tolerances/Canadian maximum residue limits (MRLs) are harmonized, with the exception of meat, fat and meat byproducts, except kidney and liver of cattle, goat, hog, horse and sheep. The method LOQ (0.02 ppm in the U.S.) is higher than the Canadian MRL (0.01 ppm). During Registration Review, HED may look into the possibility of harmonizing with Canada for the commodities with differing tolerances. It should be noted that §180.417(a)(1) lists the tolerance expression for fish and shellfish as triclopyr *per se*. §180.417 should be updated during Registration Review to include the recommended tolerance expression for fish and shellfish.

10.0 Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in the most recent bispyribac-sodium human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations¹." The OPP typically considers the highest potential exposures from the legal use of a pesticide when conducting human health risk assessments, including, but not limited to, people who obtain drinking water from sources near agricultural areas, the variability of diets within the U.S., and people who may be exposed when harvesting crops. Should these highest exposures indicate potential risks of concern, OPP further refines the risk assessments to ensure that the risk estimates are based on the best available information.

11.0 Cumulative

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for triclopyr and any other substances; and triclopyr does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that triclopyr does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

12.0 Human Studies

Past triclopyr risk assessments rely in part on data from studies in which adult human subjects were intentionally exposed to a pesticide to determine their dermal and inhalation exposure. Many such studies, involving exposure to many different pesticides, comprise generic pesticide exposure databases such as PHED, the ORETF Database, and the Agricultural Reentry Task

¹ http://www.epa.gov/compliance/environmentaljustice/resources/policy/exec_order_12898.pdf

Force (ARTF) Database. EPA has reviewed all the studies supporting these multi-pesticide generic exposure databases, and has found no clear and convincing evidence that the conduct of any of them was either fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time the research was conducted. All applicable requirements of EPA's Rule for the Protection of Human Subjects of Research (40 CFR Part 26) have been satisfied, and there is no regulatory barrier to continued reliance on these studies.

13.0 Risk Assessment Updates, Data Deficiencies, and Label Revisions

The following data deficiencies were identified for triclopyr:

Toxicology

- Subchronic Inhalation Toxicity Study (870.3465)

Residue Chemistry

- The results of a radiovalidation study to ensure the ability of the GC/MS method GRM97.02 to recover aged residues.

Occupational/Residential Exposure

- Chemical-specific TTR study (875.2100)

In addition, EPA anticipates conducting the following risk assessment updates during Registration Review:

Toxicology

- Reevaluation of toxicity endpoint/dose selection, along with the FQPA SF based on current HED policy.

Residue Chemistry

- Updated §180.417 to include the recommended tolerance expression for fish and shellfish.

Dietary Exposure

- Revised dietary exposure analysis to reflect the most recent dietary exposure models, potential revised EDWCs, and/or changes to the toxicological PODs.

Aggregate Exposure

- New aggregate risk assessment to incorporate revised dietary exposure analyses and/or revised residential exposure assessments.

Occupational/Residential Exposure

- Revised occupational and residential exposure assessments to cover all registered uses and formulations, accounting for maximum application rates, and/or policy changes will be required during Registration Review.
- Examination of the need for spray drift and volatilization risk assessments for triclopyr.

14.0 References

Memoranda Relevant to Registration Review.			
Author	Barcode	Date	Title
R. Perfetti	NA	30-OCT-1981	Triclopyr on grasses. Evaluation of analytical methods and residue data.
M. Bradley	NA	22-APR-1985	Triclopyr on grass. Amendment of 4/10/85.
G. Otakie	D195348	27-SEP-1994	PP#1F03991 - Triclopyr - DowElanco Rice Herbicide - Evaluation of Amendments Dated February 9, June 22, July 13, and July 22, 1994.
W. Smith	None	15-JUL-1996	Results of the HED Metabolism Committee Meeting Held on 7/15/96: Reassessment of Tolerances for Triclopyr on grasses, rice, meat, milk, poultry and eggs.
W. Smith	D225012	23-JUL-1996	Reregistration Case No. 2710, Chemical Nos. 116001, 116002 & 116004. Product and Residue Chemistry Chapters for the Reregistration Eligibility Decision Document (RED). CBRS No.17100. DP Barcode D225012
Davy, Mahoney & Syslo	D263769	15-MAR-2001	-
W. Smith	D261608	29-FEB-2002	Registrant's Comment on the Triclopyr Reregistration Eligibility Decision.
M. Mahoney	D281429	06-MAR-2002	-
W. Donovan	D275030	16-APR-2002	PP# 1F03935. Triclopyr, 3,5,6-Trichloro-2-pyridinol (TCP), and 2-Methoxy-3,5,6-trichloropyridine (TMP) in/on Fish and Shellfish. Anticipated Residues and Dietary Exposure Analyses for the Health Effects Division (HED) Human Health Risk Assessment.
M. Mahoney, I. Kennedy	D283715	17-JUN-2002	-
J. Swackhammer	D269448	22-JUL-2002	Occupational and Residential Exposure Characterization/Risk Assessment for Triclopyr Triethylamine for Aquatic Weed Control.
J. Tyler	D289046	31-MAR-2003	PP# 1F03935. Triclopyr, 3,5,6-Trichloro-2-pyridinol (TCP), and 2-Methoxy-3,5,6-trichloropyridine (TMP) in/on Fish and Shellfish. Results of Petition Method Validation (PMV) Review
W. Donovan	D263770	24-JULY-2004	PP# 1F03935. TRICLOPYR AQUATIC USES. Health Effects Division (HED) Risk Assessment.
W. Donovan	D268064	08-MAY-2004	PP# 1F03935. Triclopyr in Fish and Shellfish. Evaluation of Residue Data and Analytical Methods.
E. Evans	D419814	29-APR-2014	Triclopyr, salts and esters: Tier I Review of Human Incidents.
J. Leshin	TXR#0057009	TBD	Triclopyr: Summary of Hazard and Science Policy Council (HASPOC) Meeting of July 17, 2014: Recommendation on the Requirements for Subchronic Inhalation and Acute Neurotoxicity Studies.

15.0 Attachments

Attachment 1: Chemical Identity Table.

Attachment 2: Triclopyr Acute, Subchronic, and Chronic Toxicity Profile.

Attachment 3: Summary of Toxicological Doses and Endpoints for Triclopyr from the Most Recent Human Health Risk Assessment.

Attachment 4: Residential and Occupational Exposure Tables.

Attachment 5: Triclopyr International Residue Limit Status Sheet.

cc: J. Tyler (RAB1), L. Venkateshwara (RAB1), M. Perron (RAB1)

RDI: RAB1 (8/13/14), D. Vogel (8/14/14), C. Smith (8/13/14)

J. Tyler:S10943:PY-S:(703)305-5564:7509P:RAB1

Attachment 1: Chemical Identity Table.

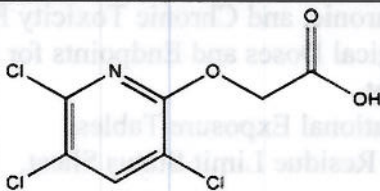
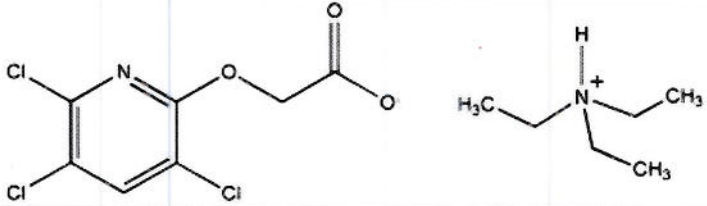
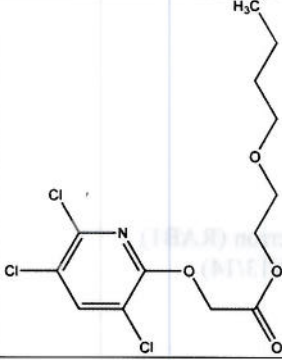
Table A1. Test Compound Nomenclature.	
Compound	
Common name	Triclopyr
IUPAC name	[(3,5,6-Trichloro-2-pyridinyl)oxy]acetic acid
CAS registry number	55335-06-3
Compound	
Common name	Triclopyr TEA
Chemical name	Triclopyr, triethylamine salt
Compound	
Common name	Triclopyr BEE
Chemical name	Triclopyr, Butoxyethyl Ester

Table A2. Physicochemical Properties of the Technical Grade Test Compound Triclopyr.		
Parameter	Value	Reference
Melting range	148-150°C	RD Memorandum, S. Mathur, 10-OCT-2001; D276420
pH	3.03 ± 0.01 at 25 C	
Density	0.308 g/mL at 20°C	
Water solubility	0.408 g/L at 20°C	
Solvent solubility	581 g/L in acetone 655 g/L in methanol	
Vapor pressure	1.5 x 10 ⁻⁶ torr at 25°C	
Dissociation constant, pK _a	Not available	
Octanol/water partition coefficient	log K _{ow} = 0.42 (pH 5)	
UV/visible absorption spectrum	Not available	

Attachment 2: Triclopyr Acute, Subchronic, and Chronic Toxicity Profile.**2.1 Toxicology Data Requirements**

Study requirements (40 CFR 158.340) for use of triclopyr. Use of the new guideline numbers does not imply that the new (1998) guideline protocols were used.

Table A3. Toxicology Data Requirements.			
Study		Technical	
		Required	Satisfied
870.1100	Acute Oral Toxicity	yes	yes
870.1200	Acute Dermal Toxicity.....	yes	yes
870.1300	Acute Inhalation Toxicity	yes	yes
870.2400	Acute Eye Irritation.....	yes	yes
870.2500	Acute Dermal Irritation.....	yes	yes
870.2600	Skin Sensitization.....	yes	yes
870.3100	90-Day Oral Toxicity in Rodents	yes	yes
870.3150	90-Day Oral Toxicity in Nonrodents	yes	yes
870.3200	21/28-Day Dermal Toxicity	yes	yes
870.3250	90-Day Dermal Toxicity	no ^{yes} ¹	--
870.3465	90-Day Inhalation Toxicity		no
870.3700a	Prenatal Developmental Toxicity (rodent)	yes	yes
870.3700b	Prenatal Developmental Toxicity (nonrodent).....	yes	yes
870.3800	Reproduction and Fertility Effects	yes	yes
870.4100a	Chronic Toxicity (rodent).....	yes	yes ²
870.4100b	Chronic Toxicity (nonrodent)	yes	yes
870.4200a	Carcinogenicity (rat)	yes	yes ²
870.4200b	Carcinogenicity (mouse).....	yes	yes
870.4300	Combined Chronic Toxicity/Carcinogenicity	yes	yes
870.5100	Mutagenicity—Bacterial Reverse Mutation Test.....	yes	yes
870.5300	Mutagenicity—Mammalian Cell Gene Mutation Test...	yes	yes
870.5xxx	Mutagenicity— Structural Chromosomal Aberrations ..	yes	yes
870.5xxx	Mutagenicity—Other Genotoxic Effects	yes	yes
870.6200a	Acute Neurotoxicity Screening Battery (rat).....	no ³	--
870.6200b	Subchronic Neurotoxicity Screening Battery (rat).....	yes	yes
870.6300	Developmental Neurotoxicity	no	--
870.7485	Metabolism and Pharmacokinetics	yes	yes
870.7600	Dermal Penetration	no	yes
870.7800	Immunotoxicity	yes	yes

1. HASPOC concluded that the subchronic inhalation study is required at this time (J. Leshin; TXR#0057009).

2. The combined chronic toxicity/carcinogenicity study satisfies the requirement of the study.

3. HASPOC concluded that the ACN is not required at this time (J. Leshin; TXR#0057009).

2.2 Triclopyr Toxicity Profiles.

Table A4. Acute Toxicity Profile – Triclopyr Acid.				
Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral	00031940	LD ₅₀ = 729 mg/kg (M) LD ₅₀ = 630 mg/kg (F)	III
870.1200	Acute dermal	00056009	LD ₅₀ > 2000 mg/kg	III

Table A5. Acute Toxicity Profile – Triclopyr Triethylamine Salt.

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral	41443301	LD ₅₀ = 1847 mg/kg	III
870.1200	Acute dermal	41443302	LD ₅₀ > 2000 mg/kg	III
870.1300	Acute inhalation	41443303	LC ₅₀ > 2.6 mg/L	III
870.2400	Primary eye irritation	41443304	corrosive	I
870.2500	Primary skin irritation	41443305	not irritating	IV
870.2600	Dermal sensitization	41443306	sensitizer	--

Table A6. Acute Toxicity Profile – Triclopyr Butoxyethyl Ester.

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral	40557004	LD ₅₀ = 803 mg/kg	III
870.1200	Acute dermal	40557005	LD ₅₀ > 2000 mg/kg	III
870.1300	Acute inhalation	40557006	LC ₅₀ > 4.8 mg/L	III
870.2400	Primary eye irritation	40557007	minimally irritating	III
870.2500	Primary skin irritation	40557008	not irritating	IV
870.2600	Dermal sensitization	40557009	sensitizer	--

Table A7. Subchronic, Chronic, and Other Toxicity Profile – Triclopyr.

Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
870.3100	90-Day Oral Toxicity in Rodents (rat) Acid form	00150378 (1984) Acceptable 0, 5, 20, 50, or 250 mg/kg/day	NOAEL = 5 mg/kg/day. LOAEL = 20 mg/kg/day based on degeneration of the proximal tubules of the kidneys.
870.3100	90-Day Oral Toxicity in Rodents (rat) Ester form	42274901 (1992) Supplementary 0, 7, 28, 70, or 350 mg/kg/day	NOAEL = not established. LOAEL = 7 mg/kg/day (F) based on decreased red blood cell content, hemoglobin content, and packed cell volume in females. Degeneration of the proximal tubules of the kidneys was seen in males at 70 and 350 mg/kg/day and females at 350 mg/kg/day (HDT).
870.3150	183-Day Oral Toxicity in Non-Rodent (dog)	00071794 (1976) Acceptable 0, 0.1, 0.5, or 2.5 mg/kg/day	NOAEL = 2.5 mg/kg/day. LOAEL = not established. Non-significant decreased rate of phenolsulfothalein (PSP) due to competition between triclopyr and PSP for renal excretion.
870.3200	21-Day Dermal Toxicity (rabbit) Ester form	42212701 (1992) Acceptable 0, 100, 500, or 1000 mg/kg/day	NOAEL = 1000 mg/kg/day. LOAEL = not established. Decreased alkaline phosphatase in both sexes at 1000 mg/kg/day and increased absolute and relative liver weights in males at 1000 mg/kg/day considered marginal and not biologically significant.

Table A7. Subchronic, Chronic, and Other Toxicity Profile – Triclopyr.			
Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
870.3700a	Prenatal Developmental in Rodent (rat) Ester form	43675801, 45168801 (1994) Acceptable/guideline 0, 5, 30, 100, or 300 mg/kg/day	Maternal NOAEL = 100 mg/kg/day. Maternal LOAEL = 300 mg/kg/day based on mortality, clinical signs, necropsy findings, decreased food consumption, increased water consumption, and increased relative kidney and liver weights Developmental NOAEL = 100 mg/kg/day. Developmental LOAEL = 300 mg/kg/day based on incidence of hydrocephalus, cleft palate, microphthalmia/anophthalmia, retinal folds, thin diaphragm/protrusion of the liver, decrease fetal weight, and visceral and skeletal anomalies and variants.
870.3700a	Prenatal Developmental in Rodent (rat) Salt form	43217602 (1994) Acceptable/guideline 0, 30, 100, or 300 mg/kg/day	Maternal NOAEL = 100 mg/kg/day. Maternal LOAEL = 300 mg/kg/day based on mortality. Developmental NOAEL = 100 mg/kg/day. Developmental LOAEL = 300 mg/kg/day based on decreased fetal weights, increased fetal and litter incidence of skeletal anomalies, and increased fetal incidence of unossified sternebrae.
870.3700a	Prenatal Developmental in Rodent (rat) Acid form	00072441, 41688301, 92189024 (1979) Acceptable/guideline 0, 50, 100, or 200 mg/kg/day	Maternal NOAEL = not established. Maternal LOAEL = 50 mg/kg/day based on increased clinical signs. Developmental NOAEL = 100 mg/kg/day. Developmental LOAEL = 200 mg/kg/day based on increased incidence of fetuses and litters with retarded ossification of skull bones and two litters (one fetus per litter) with cleft palate and brachycephaly.
870.3700b	Prenatal Developmental in Non-Rodent (rabbit) Ester form	43217601 (1994) Core-minimum 0, 10, 30, or 100 mg/kg/day	Maternal NOAEL = 30 mg/kg/day. Maternal LOAEL = 100 mg/kg/day based on mortality. Developmental NOAEL = 30 mg/kg/day. Developmental LOAEL = 100 mg/kg/day based on decreased total live fetuses and increased total fetal deaths and increased fetal and/or litter incidence of skeletal anomalies and variants.
870.3700b	Prenatal Developmental in Non-Rodent (rabbit) Salt form	43217603 (1994) Core-minimum 0, 10, 30, or 100 mg/kg/day	Maternal NOAEL = 30 mg/kg/day. Maternal LOAEL = 100 mg/kg/day based on mortality, abortions, decreased food efficiency, increased liver and kidney weights. Developmental NOAEL = 30 mg/kg/day. Developmental LOAEL = 100 mg/kg/day based on decreased live fetuses and increased embryonic deaths due to abortions.
870.3800	Reproduction and Fertility Effects (rat) Acid form	43545701 Acceptable/guideline 0, 5, 25, or 250 mg/kg/day	Parental NOAEL = 5 mg/kg/day. Parental LOAEL = 25 mg/kg/day based on increased incidence of proximal tubular degeneration in both sexes. Offspring NOAEL = 5 mg/kg/day. Offspring LOAEL = 25 mg/kg/day based on increased incidences of F2 pups with exencephaly and ablepharia.
870.4100a	228-Day Toxicity Study (dog) Acid form	00071794(1976) Core-minimum 0, 5, 10 or 20 mg/kg/day	NOAEL = 10 mg/kg/day. LOAEL = 20 mg/kg/day based on decreased hematological parameters, changes in clinical chemistry and liver histopathology.

Table A7. Subchronic, Chronic, and Other Toxicity Profile – Triclopyr.			
Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
870.4100b	1-Year Chronic Toxicity (dog)	41200301(1988) Acceptable (with 228 day study) 0, 5, 10, or 20 mg/kg/day	NOAEL = 5 mg/kg/day. LOAEL = not established. Changes in clinical chemistry are due to a physiological response of the dog based on limited ability of the dog to excrete organic acids at higher plasma concentration.
870.4200a	Carcinogenicity (rat)	See 870.4300	See 870.4300
870.4200b	Carcinogenicity (mouse)	40356601 (1987) Core-minimum 0, 5.09/5.55, 26.5/28.6, or 135/143 mg/kg/day (M/F)	NOAEL = 26.5/28.6 mg/kg/day (M/F). LOAEL = 135/143 mg/kg/day (M/F)] based on decreased weight gains. No evidence of carcinogenicity in males, but females had a significant trend (p<0.05) for mammary gland adenocarcinomas.
870.4300	Combined Chronic Toxicity/ Carcinogenicity (rat)	40107701 (1987) Core-minimum 0, 3, 12 or 36 mg/kg/day	NOAEL = 36 mg/kg/day. LOAEL = not established. Marginal increase in proximal tubular degeneration observed at 6 months. Increase in adrenal gland pheochromocytoma in males and significant trend (p<0.05) for mammary gland adenocarcinomas in females.
870.5265	Gene mutation Ester form	41732202	Non-mutagenic up to 5,000 µg/plate or cytotoxic levels, in presence and absence of activation, in <i>S. typhimurium</i> strains TA98, TA100, TA1535, and TA1537.
870.5265	Gene mutation Acid form	00031939 (1975) Supplementary	Non-mutagenic up to 10,000 µg/plate or cytotoxic levels, in presence and absence of activation, in <i>S. typhimurium</i> strains TA98, TA100, TA1535, TA1537, and TA1538.
870.5300	Gene mutation Acid form	00038408 (1980) Acceptable	No evidence of growth inhibition for the repair competent (H17) or repair deficient (M45) <i>B. subtilis</i> bacterial strains when tested up to 2,000 µg/disk.
870.5300	Gene mutation Acid form	00057085 (1973) Acceptable	Negative for mutagenicity at doses up to 70 mg/kg in ICR random bred mice when tested against indicator organisms.
870.5395	<i>In vivo</i> Cytogenetic Assay (rat) Acid form	00057086 (1973) Acceptable	Negative for chromosomal aberrations in the cytogenetic assay when administered as a single dose or for 5 days up to 70 mg/kg/day.
870.5395	<i>In vivo</i> Mouse Micronucleus Ester form	41747101 (1990) Acceptable	Not clastogenic up to 600 mg/kg (HDT).
870.5450	Dominant lethal assay (mouse) Acid form	00028996 (1980) Acceptable	Negative at doses up to 70 mg/kg/day.
870.5450	Dominant lethal assay (rat) Acid form	00057087 (1973) Acceptable	Negative at doses up to 70 mg/kg/day.
870.5550	Unscheduled DNA synthesis Ester form	41747102 (1990) Acceptable	Did not cause DNA damage or inducible repair.

Table A7. Subchronic, Chronic, and Other Toxicity Profile – Triclopyr.

Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
870.5550	Unscheduled DNA synthesis Acid form	40057702 (1986) Acceptable	No evidence of unscheduled DNA synthesis.
870.6200	Subchronic Neurotoxicity Screening Battery (rat) Acid form	49306303 (2012) Acceptable/guideline 0, 5, 25, or 200 mg/kg/day	NOAEL = 25 mg/kg/day. LOAEL = 200 mg/kg/day based on decreased body weights and food consumption in males.
870.7485	Metabolism and Pharmacokinetics	41353001 (1988) Acceptable/guideline 3 or 60 mg/kg/day	Regardless of dose level or route of administration, triclopyr was well absorbed with peak plasma levels reached within 3-4 hours. Radioactivity in the tissues at 72 hours was minimal (<0.54%). At the low dose, >90% of the radioactivity was excreted within 24 hours primarily via the urine. The high dose yielded similar overall results except that urinary elimination was decreased between 0-12 hours due to saturation of renal excretion mechanisms. Unmetabolized parent represented >90% of the urinary radioactivity.
870.7600	Dermal Penetration Study (Human) Ester form	45253601 (1989) Supplementary 3.7 mg/kg; 8 hour exposure; observed up to 84 hours after dosing	In an oral and dermal pharmacokinetics study of triclopyr in human volunteers, triclopyr was administered orally and dermally to six human volunteers. More than 80% of the administered dose was found as unchanged triclopyr in the urine. An average of 1.65% of the dermally applied dose was recovered in the urine and represented dermal penetration of triclopyr.
870.7600	Dermal Penetration Study (rabbit) Acid form	00153805 (1981) Acceptable 2 g/kg	1.5% of an applied dose absorbed through the skin.
870.7800	Immunotoxicity	49433001 (2011) Acceptable/guideline 0, 10, 50, or 250 mg/kg/day	Systemic NOAEL = 50 mg/kg/day. Systemic LOAEL = 250 mg/kg/day based on decreased body weights and food consumption. Immunotoxicity NOAEL = 250 mg/kg/day. Immunotoxicity LOAEL = not established.

Attachment 3: Summary of Toxicological Doses and Endpoints for Triclopyr from the Most Recent Human Health Risk Assessment.

Table A8. Summary of Toxicological Doses and Endpoints for Triclopyr for Use in Dietary and Non-Occupational Human Health Risk Assessments.

Exposure/ Scenario	POD	Uncertainty/FQP A Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General Population including infants and children)	NOAEL = 100 mg/kg/day	UF _A = 10X UF _H = 10X FQPA = 1X	aRfD = 1.0 mg/kg/day aPAD = 1.0 mg/kg/day	<u>Developmental Rat Toxicity Study with ester</u> Maternal LOAEL = 300 mg/kg/day based on mortality, clinical signs, necropsy findings, decreased food and water consumption, and increased kidney and liver weights.
Acute Dietary (Females 13-50 years old)	NOAEL = 5 mg/kg/day	UF _A = 10X UF _H = 10X FQPA = 1X	aRfD = 0.05 mg/kg/day aPAD = 0.05 mg/kg/day	<u>Two-Generation Rat Reproduction Study with acid</u> LOAEL = 25 mg/kg/day based on increased incidence of rare malformations (exencephaly and ablepharia).
Chronic Dietary (All Populations)	NOAEL = 5 mg/kg/day	UF _A = 10X UF _H = 10X FQPA = 1X	cRfD = 0.05 mg/kg/day cPAD = 0.05 mg/kg/day	<u>Two-Generation Rat Reproduction Study with acid</u> LOAEL = 25 mg/kg/day based on degeneration of the proximal renal tubules.
Incidental Oral Short-Term (1-30 days)	NOAEL = 100 mg/kg/day	UF _A = 10X UF _H = 10X FQPA = 1X	Residential LOC for MOE = 100	<u>Co-critical Studies: Developmental Rat Toxicity Studies with ester and salt</u> LOAEL = 300 mg/kg/day based on mortality and clinical signs.
Incidental Oral Intermediate-Term (1-6 months)	NOAEL = 5 mg/kg/day	UF _A = 10X UF _H = 10X FQPA = 1X	Residential LOC for MOE = 100	<u>Subchronic Oral Rat Toxicity Study with acid</u> LOAEL = 20 mg/kg/day based on degeneration of the proximal renal tubules.
Dermal Short-Term (1-30 days)	NOAEL = 5.0 mg/kg/day Dermal absorption factor = 2%	UF _A = 10X UF _H = 10X FQPA = 1X	Residential LOC for MOE = 100	<u>Two-Generation Rat Reproduction Study with acid</u> LOAEL = 25 mg/kg/day based on increased incidence of rare malformations (exencephaly and ablepharia).
Dermal Intermediate-Term (1-6 months)	NOAEL = 5.0 mg/kg/day Dermal absorption factor = 2%	UF _A = 10X UF _H = 10X FQPA = 1X	Residential LOC for MOE = 100	<u>Co-critical Studies: Two-Generation Rat Reproduction Study with acid and Subchronic Oral Rat Toxicity Study with acid</u> LOAEL = 20 mg/kg/day (subchronic rat) and 25 mg/kg/day (two-generation reproduction) based on degeneration of the proximal renal tubules in both studies.
Dermal Long-Term (>6 months)	NOAEL = 5.0 mg/kg/day Dermal absorption factor = 2%	UF _A = 10X UF _H = 10X FQPA = 1X	Residential LOC for MOE = 100	<u>Two-Generation Rat Reproduction Study with acid</u> LOAEL = 25 mg/kg/day based on increased incidence of rare malformations (exencephaly and ablepharia).
Inhalation Short-Term (1-30 days)	NOAEL = 5 mg/kg/day Inhalation assumed equivalent to oral	UF _A = 10X UF _H = 10X FQPA = 1X	Residential LOC for MOE = 100	<u>Two-Generation Rat Reproduction Study with acid</u> LOAEL = 25 mg/kg/day based on increased incidence of rare malformations (exencephaly and ablepharia).

Table A8. Summary of Toxicological Doses and Endpoints for Triclopyr for Use in Dietary and Non-Occupational Human Health Risk Assessments.

Exposure/ Scenario	POD	Uncertainty/FQP A Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Inhalation Intermediate-Term (1-6 months)	NOAEL = 5 mg/kg/day	UF _A = 10X UF _H = 10X FQPA = 1X	Residential LOC for MOE = 100	<u>Co-critical Studies: Two-Generation Rat Reproduction Study with acid and Subchronic Oral Rat Toxicity Study with acid</u> LOAEL = 20 mg/kg/day (subchronic rat) and 25 mg/kg/day (two-generation reproduction) based on degeneration of the proximal renal tubules in both studies.
Inhalation Long-Term (>6 months)	NOAEL = 5 mg/kg/day	UF _A = 10X UF _H = 10X FQPA = 1X	Residential LOC for MOE = 100	<u>Co-critical Studies: Two-Generation Rat Reproduction Study with acid and Subchronic Oral Rat Toxicity Study with acid</u> LOAEL = 20 mg/kg/day (subchronic rat) and 25 mg/kg/day (two-generation reproduction) based on degeneration of the proximal renal tubules in both studies.
Cancer (oral, dermal, inhalation)	Classified as a "Group D Chemical – unable to be classified as to human carcinogenicity."			

Point of departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. FQPA SF = FQPA Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

Table A9. Summary of Toxicological Doses and Endpoints for Triclopyr for Use in Occupational Human Health Risk Assessments.

Exposure/ Scenario	POD	Uncertainty Factors	LOC for Risk Assessment	Study and Toxicological Effects
Dermal Short-Term (1-30 days)	NOAEL = 5.0 mg/kg/day Dermal absorption factor = 2%	UF _A = 10X UF _H = 10X	Occupational LOC for MOE = 100	<u>Two-Generation Rat Reproduction Study with acid</u> LOAEL = 25 mg/kg/day based on increased incidence of rare malformations (exencephaly and ablepharia).
Dermal Intermediate-Term (1-6 months)	NOAEL = 5.0 mg/kg/day Dermal absorption factor = 2%	UF _A = 10X UF _H = 10X	Occupational LOC for MOE = 100	<u>Co-critical Studies: Two-Generation Rat Reproduction Study with acid and Subchronic Oral Rat Toxicity Study with acid</u> LOAEL = 20 mg/kg/day (subchronic rat) and 25 mg/kg/day (two-generation reproduction) based on degeneration of the proximal renal tubules in both studies.
Dermal Long-Term (>6 months)	NOAEL = 5.0 mg/kg/day Dermal absorption factor = 2%	UF _A = 10X UF _H = 10X	Occupational LOC for MOE = 100	<u>Two-Generation Rat Reproduction Study with acid</u> LOAEL = 25 mg/kg/day based on increased incidence of rare malformations (exencephaly and ablepharia).
Inhalation Short-Term (1-30 days)	NOAEL = 5 mg/kg/day Inhalation assumed equivalent to oral	UF _A = 10X UF _H = 10X	Occupational LOC for MOE = 100	<u>Two-Generation Rat Reproduction Study with acid</u> LOAEL = 25 mg/kg/day based on increased incidence of rare malformations (exencephaly and ablepharia).
Inhalation Intermediate-Term (1-6 months)	NOAEL = 5 mg/kg/day Inhalation assumed equivalent to oral	UF _A = 10X UF _H = 10X	Occupational LOC for MOE = 100	<u>Co-critical Studies: Two-Generation Rat Reproduction Study with acid and Subchronic Oral Rat Toxicity Study with acid</u> LOAEL = 20 mg/kg/day (subchronic rat) and 25 mg/kg/day (two-generation reproduction) based on degeneration of the proximal renal tubules in both studies.
Inhalation Long-Term (>6 months)	NOAEL = 5 mg/kg/day Inhalation assumed equivalent to oral	UF _A = 10X UF _H = 10X	Occupational LOC for MOE = 100	<u>Co-critical Studies: Two-Generation Rat Reproduction Study with acid and Subchronic Oral Rat Toxicity Study with acid</u> LOAEL = 20 mg/kg/day (subchronic rat) and 25 mg/kg/day (two-generation reproduction) based on degeneration of the proximal renal tubules in both studies.
Cancer (oral, dermal, inhalation)	Classified as a "Group D Chemical – unable to be classified as to human carcinogenicity."			

Point of departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. MOE = margin of exposure. LOC = level of concern.

Attachment 4: Residential and Occupational Exposure Tables.**4.1 Residential Exposure****Table A10. Summary of Residential Use Patterns, Formulations, and Application Rates for Uses of Triclopyr.**

Chemical Name	Registration Number and Product Name	Use Site	Formulation and Percent Active Ingredient	Application method	Maximum App Rate
Triclopyr, butoxyethyl ester (116004)	62719-67 Turflon® D	Recreation area lawns and residential lawn	Emulsifiable Concentrate (EC) 16.5%	Ground (sprayer)	1.386 lb ai/A
Triclopyr triethylamine salt (116002)	62719-92 Confront®	Golf course turf and Ornamental lawn and turf	EC 33%	Ground (sprayer)	0.78375 lb ai/A
Triclopyr triethylamine salt (116002)	62719-217 XRM-5202	Golf course turf and Ornamental lawn and turf and paved areas (private roads and sidewalks)	EC 3.8%	Ground (sprayer)	0.1843 lb ai/A or 0.00287969 lb ai/ gal
Triclopyr triethylamine salt (116002)	62719-226 Dow AgroSciences Brush & Weed Herbicide	For the control of woody plants, vines and broadleaf weeds around homes, cabins, fences, walkways and other non-crop areas. Contains Hammer Herbicide. This product is for outdoor residential use only.	Soluble Liquid (SL) 8.8%	Ground, hose end sprayer, tank type sprayer, backpack sprayer	9 lb ae/A
Triclopyr triethylamine salt (116002)	62719-257 Turflon Amine	Ornamental Lawns and Turf	SL 44.4%	Ground broadcast equipment, handgun application equipment	2.109 lb ai/A
Triclopyr, butoxyethyl ester (116004)	62719-566 Turflon Ester Ultra	Golf course turf, ornamental lawn and turf	EC 60.5%	Ground (sprayer)	1.481025 lb ai /A
Triclopyr triethylamine salt (116002)	62719-599 GF-121	Golf course turf, ornamental lawn and turf, , recreation area lawns and residential lawn	Emulsion, oil in water 3.86%	Ground, control droplet applicator, sprayer	0.18721 lb ai /A or 0.00438773 lb ai / gal

Summary of Previous Residential Handler Assessments (Memo, J. T. Swackhammer, 22-JUL-2002; D269448)**Table A11. Uses of Triclopyr – Summary of Residential Handler Exposure and Risks.**

Exposure Scenario Assessed		DP#	Formulation	App. Rate ¹	Daily Amount Treated	Unit Exposure		MOE		Combined MOE
						Dermal (mg/lb ae handled)	Inhalation (mg/lb ae handled)	Dermal	Inhalation	
Mixer/Loader/Applicator	Broadcast granular spreader	D269448	Granular	0.56 lbs ae/A	0.5 A/day	Short pants, short sleeves: 0.68	0.00091	Not given	Not given	74,000
Mixer/Loader/Applicator	Spot treatment, hose-end sprayer, "mix your own"	D269448	Liquid	0.00006 lb ae/ft ²	1,000 ft ²	Short pants, short sleeves: 11	0.016	Not given	Not given	With gloves: 21,000

1. Application rates based on the following labels - Lilly/Miller Blackberry & Brush Killer-TEA, SC, Riverdale Horsepower Lawn Weed Killer (commercial)-TEA, granular, Turf Fertilizer Contains Confront- TEA, granular, Turflon II Amine-TEA, SC, Turflon D-BEE, EC, Crossbow LV-BEE, EC. Note, Riverdale Horsepower Lawn Weed Killer (commercial)-TEA, granular is not included in Table A10 because it is not a DOW product. Turf Fertilizer Contains Confront- TEA is now is a non-residential product.

Summary of Previous Residential Post-Application Assessments (Memo, J. T. Swackhammer, 22-JUL-2002; D269448)

Table A12. Exposure and Risk Assessment for Incidental Ingestion of Toddlers Following Application of Triclopyr to Residential Lawns.¹

Granular Ingestion				
% Triclopyr in formulation (as acid equivalents)		Ingestion Rate (g/d)	PDR (mg/kg bw/d) ²	MOE ³
0.36		0.3	0.072	1,000
Hand-to-mouth, Object-to-mouth, and Soil Ingestion				
Activity	AR (lb.a.e./A) ⁴	Residue Estimate ⁵	PDR (mg/kg bw/d) ⁶	MOE ⁷
Hand-to- mouth	0.54	DFR: 0.303 ·g/cm ²	0.00808	Short-term: 8,900
Object-to- mouth		DFR: 1.21 ·g/cm ²	0.00202	Short-term: 36,000
Soil Ingestion		Soil residue: 4.06 ·g/g soil	2.71 x 10 ⁻⁵	Short-term: 2.7 x 10 ⁶ Intermediate-term: 180,000

1. Sources: Standard Operating Procedures for Residential Exposure Assessments, Draft, December 17, 1997 and Exposure SAC Policy No. 11, Feb. 22, 2001; Recommended Revisions to the SOPs for Residential Exposure.

2. Granular ingestion PDR = 0.3 g/dx 1000 mg/g x 0.0036 lb ae/lb x 1/15 kg = 0.072 mg/kg bw/d.

3. Granular ingestion MOE = (acute dietary NOAEL, 72 mg/kg/d)/0.072 mg/kg bw/d = 1000.

4. AR = maximum application rate on Turflon II Amine label (EPA Reg. No. 62719-75) for residential lawn treatment by PCO.

5. Residue estimates based on the following protocol from the Residential SOPs:

a. Hand-to-mouth DFR = 0.54 lb ai/A x 0.05 x (4.54 x 10⁸ ·g/lb ai) x (2.47 x 10⁻⁸ A/cm²) = 0.303 ·g/cm².

b. Object-to-mouth DFR = 0.54 lb ai/A x 0.20 x (4.54 x 10⁸ ·g/lb ai) x (2.47 x 10⁻⁸ A/cm²) = 1.21 ·g/cm².

c. Soil Residue = 0.54 lb ai/A x fraction of residue in soil (100%)/cm x (4.54 x 10⁸ ·g/lb ai) x (2.47 x 10⁻⁸ A/cm²) x 0.67 cm³/g = 4.06 ·g/g soil.

6. Potential Dose Rate (PDR; normalized to body weight of toddler):

a. Short-term Hand-to-mouth PDR = (0.303 ·g/cm² x 0.50 x 20 cm²/event x 20 events/hr x 10⁻³ mg·g x 2 hrs/d)/15 kg = 0.00808 mg/kg bw/d .

b. Object-to-mouth PDR = (1.21 ·g/cm² x 25 cm²/d x 10⁻³ mg·g)/15 kg = 0.00202 mg/kg bw/d

c. Soil Ingestion PDR = (4.06 ·g/g soil x 100 mg soil/d x 10⁻⁶ g·g)/15 kg = 2.71 x 10⁻⁵ mg/kg bw/d

7. MOE = NOAEL/PDR, where the short-term incidental oral NOAEL = 100 mg/kg/d (72 mg/kg/d as acid equivalents) and intermediate-term incidental oral NOAEL (soil ingestion only) = 5 mg/kg/d; HED's LOC is for MOEs < 100 (residential).

Table A13. Post-Application Dermal Exposure and Risk Assessment for Residential Lawns Treated with Registered Triclopyr End-Use Products.¹

Exposure Scenario	AR (lbs ae/A) ²	DFR on Day 0 (g/cm ²) ³	PDR (mg/kg bw/d) ⁴	Short-term Dermal MOE ⁵
Adults – Female Age 13-50	0.54	0.303	0.00293	1,700
Toddler			0.0042	1,200

1. Sources: Standard Operating Procedures for Residential Exposure Assessments, Draft, December 17, 1997 and Exposure SAC Policy No. 11, Feb. 22, 2001; Recommended Revisions to the SOPs for Residential Exposure.

2. AR = maximum application rate by LCO performing residential lawn treatment.

3. DFR = 0.54 lb ai/A x 0.05 x (4.54 x 10⁸ ·g/lb ai) x (2.47 x 10⁻⁸ A/cm²) = 0.303 ·g/cm².

4. PDR = (0.303 ·g/cm² x 0.001 mg·g x TC (cm²/hr) x 2 hrs/d x % dermal absorption (2%)/BW (60 kg for adult females and 15 kg for toddlers). Note: TC for adults, short-term = 14,500 cm²/hr and TC for toddlers, short-term = 5,200 cm²/hr.

5. MOE = NOAEL/PDR, where the short-term dermal NOAEL = 5 mg/kg/day. HED's LOC is for MOEs < 100.

Table A14. Application Golfer Exposure and Risk Assessment for Registered Uses of Triclopyr at Golf Courses.

Exposure Scenario	AR (lb a.e./A)	TC (cm ² /hr)	TTR ¹ (ug/cm ²)	Dermal Exposure (DE; mg/kg/day) ²	Short-term Dermal MOE ³
Adult Female Golfer	0.54	500	0.303	2.02 x 10 ⁻⁴	25,000
Child Golfer				3.11 x 10 ⁻⁴	16,000

1. TTR = application rate (lb a.i./A) x 5% available as dislodgeable residue x 4.54E+8 ug/lb x 2.47E-8 A/cm²

2. DE = TTR (ug/cm²) x TC (cm²/hr) x 4 hrs/day x 0.001 mg/ug x 1/ BW x %dermal absorption; BW= 60kg for adult-females and 39 kg for children; dermal absorption = 2%.

3. MOE = NOAEL/ ADD; short-term dermal NOAEL = 5 mg/kg bw/day. HED's LOC for recreational dermal exposures is for MOEs < 100.

Table A15. Post-Application Swimmer Exposure and Risk Assessments for Proposed Use of Triclopyr TEA at Aquatic Sites.

Exposure Scenario	AR (lb a.e./A)	Concentration in water (ppm)	Potential Dose Rate (PDR; oral) ¹ or Absorbed Dose Rate (ADR; dermal) ² (mg/kg/day)	Short-term MOE ³
Incidental Ingestion, Adult-females, 13-50	154	2.5	0.0104	6,900
Incidental Ingestion, child			0.00862	8,400
Incidental ingestion, toddler			0.0167	4,300
Dermal, Adult- female			1.40×10^{-5}	360,000
Dermal, child			8.20×10^{-6}	610,000
Dermal, toddler			1.58×10^{-5}	320,000

1. PDR, incidental oral exposure = concentration, C_w (mg/L) x ingestion rate, IgR (L/hr) x exposure time, ET (hrs/d) x 1/BW (adult-female=60 kg; child = 29 kg; toddler = 15 kg)

2. ADR= concentration, C_w (mg/L) x surface area exposed, SA (cm²) x ET x K_p (cm/hr) x 1/1000 cm³ x %Dermal Absorption (correct to oral equivalent) x 1/BW, where K_p is estimated as follows: $\log K_p = -2.72 + 0.71 \log K_{ow} - 0.0061 MW$; $K_{ow} = 5$, $MW = 256.5$.

3. MOE = NOEL/PDR; short-term incidental oral NOEL = 100 (72 mg/kg bw/d as acid equivalents) short-term dermal NOEL = 5 mg/kg bw/d. The LOC for short-term recreational exposures is for MOEs < 100.

4.2 Occupational Exposure

Table A16. Summary of Occupational Use Patterns, Formulations, and Application Rates for Uses of Triclopyr.¹

Chemical Name	Registration Number and Product Name	Crop/Use Site	Formulation and Percent ai	Application method	Maximum App Rate (lb ai/A)	REI
Triclopyr triethylamine salt (116002)	62719-37 Garlon® 3A	Range and pasture, forests and non-crop areas, and applications to grazed areas, and establishment and maintenance of wildlife openings, and in Christmas tree plantations and aquatic sites.	SL 44%	Ground, aerial (helicopter)	9 lb ae/A	48 hr
Triclopyr, butoxyethyl ester (116004)	62719-40 Garlon® 4	Non-crop industrial manufacturing and storage sites; rights-of way; conservation reserve program (CRP); forests and in the establishment and maintenance of wildlife openings. Use on these sites may include application to grazed areas.	EC 61.6%	Ground, aerial, backpack sprayer, power sprayer, high and low volume sprayer	8 lb ae/A	12 hr
Triclopyr, butoxyethyl ester (116004)	62719-67 Turflon® D	Commercial/industrial lawns, ornamental sod farm (turf).	EC 16.5%	Ground	1.386 lb ai/A	12 hours
Triclopyr, butoxyethyl ester (116004)	62719-70 Remedy®	Rangeland, permanent grass pastures, and CRP acres.	EC 61.6%	Ground, aerial, backpack sprayer	2.0328 lb/A	Not specified
Triclopyr triethylamine salt (116002)	62719-92 Confront®	Golf course turf and Ornamental lawn and turf	EC 33%	Ground, sprayer	0.78375 lb ai/A	48 hours
Triclopyr, butoxyethyl ester (116004)	62719-176 Pathfinder® II	Rangeland and permanent pastures and in non-crop areas including industrial manufacturing and storage sites, rights-of-way.	Liquid 13.6%	Backpack or knapsack sprayer using low pressure and a solid cone or flat fan nozzle	8 lb ae/A	12 hours
Triclopyr triethylamine salt (116002)	62719-187 Renovate®	Aquatic areas/water	SL 44.4 %	Spray boom, handgun, or other suitable equipment mounted on a	6 lb ae/A	48 hours

Table A16. Summary of Occupational Use Patterns, Formulations, and Application Rates for Uses of Triclopyr.¹

Chemical Name	Registration Number and Product Name	Crop/Use Site	Formulation and Percent ai	Application method	Maximum App Rate (lb ai/A)	REI
				boat or vehicle, helicopter.		
Triclopyr triethylamine salt (116002)	62719-215 Grandstand R	Rice	SL 44.4 %	Ground, aerial (helicopter)	0.375 lb ae/A	48 hours
Triclopyr triethylamine salt (116002)	62719-217 XRM-5202	Golf course turf and ornamental lawn and turf and paved areas (private roads and sidewalks)	EC 3.8%	Ground (sprayer)	0.1843 lb /A or .00287969 lb / 1 gal	Not specified
Triclopyr triethylamine salt (116002)	62719-226 Dow AgroSciences Brush & Weed Herbicide	Forests and industrial non-crop areas, including manufacturing and storage sites, rights-of-way, and in Christmas tree plantations. Use within production forests and industrial non-crop sites may include applications to control target vegetation in and around standing water sites, such as marshes, wetlands and the banks of ponds and lakes.	Soluble Liquid (SL) 8.8%	Ground, aerial, hose end sprayer, tank type sprayer, backpack sprayer	9 lb ae/A	48 hours
Triclopyr, butoxyethyl ester (116004)	62719-258 Turflon Ester	Golf course turf, ornamental lawn and turf and ornamental sod farm turf	EC 61.6%	Sprayer	2.7104 lb ai/A	12 hr
Triclopyr, butoxyethyl ester (116004)	62719-260 Crossbow	Rangeland, permanent grass pastures, CRP acres, fencerows, non-irrigation ditch banks, roadsides, other non-crop areas, and industrial sites.	EC 16.5%	Ground, aerial	1.386 lb ai/A	Until sprays have settled
Triclopyr triethylamine salt (116002)	62719-262 Contains Confront	To be applied only under the direct supervision of licensed pesticide applicators responsible for turf weed control programs * Selectively controls annual and perennial broadleaf weeds * Provides a feeding of fertilizer	Fertilizer 0.5%	Ground spreader	0.75 lb ai/A	Until dusts have settled
Triclopyr triethylamine salt (116002)	62719-337 Redeem R&P	Rangeland and permanent grass pastures, non-crop areas such as fencerows, non-irrigation ditchbanks, roadsides and around farm buildings, and CRP acres.	EC 33%	Ground, aerial, handheld	1.6 lb ai/A	48 hours
Triclopyr triethylamine salt (116002)	62719-338 Crossbow SF	Rangeland, permanent grass pastures, Christmas tree plantations, CRP acres, and non-crop areas such as fencerows, nonirrigation ditchbanks, roadsides and around farm buildings.	SL 44.4%	Ground, sprayer	12.654 lb ai/A	48 hours
Triclopyr, butoxyethyl ester (116004)	62719-477 Pasturegard	Rangeland and permanent pastures, CRP acres, fence rows, and in non-crop areas using broadcast, foliar, basal bark or cut stump individual plant treatment methods.	EC 25%	Ground, aerial, sprayer	2.09 lb ai/A and 0.0418 lb ai/gal	12 hours
Triclopyr triethylamine salt (116002)	62719-511 Garlon EV	Turfgrass, and on non-crop areas including industrial sites, rights-of-way, non-irrigation ditch banks, natural areas and grazed areas in and around these sites.	EW (emulsion, oil in water) 16.1%	Sprayer, backpack sprayer, handheld sprayer, low and high volume sprayer	2.0769 lb/a	48 hours

Table A16. Summary of Occupational Use Patterns, Formulations, and Application Rates for Uses of Triclopyr.¹

Chemical Name	Registration Number and Product Name	Crop/Use Site	Formulation and Percent ai	Application method	Maximum App Rate (lb ai/A)	REI
Triclopyr, butoxyethyl ester (116004)	62719-527 Garlon 4 Ultra	Industrial, manufacturing and storage sites; rights-of-way and in the establishment and maintenance of wildlife openings. Use on these sites may include application to grazed areas.	EC 60.5%	Ground, aerial	8 lb ae/A	12 hours
Triclopyr triethylamine salt (116002)	62719-528 GF 1249	Non-crop areas including forest planting sites, industrial and manufacturing sites; rights-of-way and wildlife openings in forest and non-crop areas.	EC 22.2%	Ground, aerial	Spot: 1 lb ae/A Broadcast 0.5 lb ae/A	48 hour
Triclopyr, butoxyethyl ester (116004)	62719-552 Remedy Ultra Herbicide	Rangeland, permanent grass pastures, and CRP acres (including fence rows and non-irrigation ditch banks within these areas).	EC 60.5%	Ground, aerial	2 lb ai/A	Until sprays have dried
Triclopyr, butoxyethyl ester (116004)	62719-553 Forestry Garlon XRT	Non-crop areas including industrial manufacturing and storage sites, rights-of-way and in the establishment and maintenance of wildlife openings. Use on these sites may include application to grazed areas.	EC 83.9 %	Ground, aerial (helicopter)	2 lb ai/A	12 hours
Triclopyr, butoxyethyl ester (116004)	62719-566 Turflon Ester Ultra	Golf course turf, ornamental lawn and turf and ornamental sod farm turf	EC 60.5%	Ground, sprayer	1.481025 lb ai /Aa	12 hours
Triclopyr triethylamine salt (116002)	62719-572 Milestone VM Plus	<ul style="list-style-type: none"> • Rangeland, permanent grass pastures (including grasses grown for hay*), CRP, • forests, and • non-cropland areas. *Hay from grass treated with Milestone VM Plus within the preceding 18-months can only be used on the farm or ranch where the product is applied unless allowed by supplemental labeling.	EC 16.2%	Ground, aerial	1.64 lb ai/A	Until sprays have dried
Triclopyr triethylamine salt (116002)	62719-599 GF-121	Commercial/industrial lawns, golf course turf, ornamental lawn and turf, ornamental sod farm.	Emulsion, oil in water 3.86%	Ground, control droplet applicator, sprayer	0.18721 lb ai/A or 0.00438773 lb ai/gal	48 hours
Triclopyr, butoxyethyl ester (116004)	62719-637 Pasturegard HL	Rangeland and permanent pastures, CRP acres, fence rows, and in non-crop areas using broadcast, foliar, basal bark or cut stump individual plant treatment methods.	EC 45.1%	Ground, aerial, handheld	2.2 lb ai/A	12 hours

¹ See e-mail correspondence from T. Jones-Jefferson, 6/11/2014 to S. Snyderman, EPA.

Summary of Previous Occupational Handler Assessment (Memo, J. Swackhammer, 22-JUL-2002; D269448)

Table A17. Summary of Representative Occupational Exposure Scenarios and Risks for Conventional Uses of Triclopyr.¹

Exposure Scenario Assessed		Formulation	App. Rate	Daily Amount Treated	Unit Exposure		Combined MOE
					Dermal (mg/lb ae handled)	Inhalation (mg/lb ae handled)	
Mixer/Loader	Open pour supporting aerial applications (by helicopter) surface weed control		6 lbs ae/A	100 A	Baseline: 2.9 SL with gloves: 0.023	0.0012	Baseline: 8.5 With gloves: 300
	Open pour supporting boat application for submersed weed control		154 lbs ae/A	10 A	Baseline: 2.9 SL with gloves: 0.023	0.0012	Baseline: 3.3 With gloves: 120
Mixer/Loader/Applicator	Backpack sprayer, wetland weed control		1.8 lb ae/day	40 gallons/day	SL with gloves: 0.0015	0.0009	With gloves: 2,100
Applicator	Handwand from boat or truck surface weed control and wetland weed control		6 lbs ae/A	10 A	Baseline: 1.3 SL with gloves: 0.39	0.039	Baseline: 170 With gloves: 430

Summary of Previous Occupational Post Application Assessments (Memo, J. Swackhammer, 22-JUL-2002; D269448): Personnel entering wetland sites following applications could potentially have short-term dermal exposures. No post-application exposure is anticipated from floating or submersed weed control treatment. It is anticipated that post-application entry into treated wetland sites may consist of personnel checking on the efficacy of treatments (i.e., scouting or post-application survey). Table A18 presents the results of the post-application assessment.

Table A18. Post-Application Worker Exposure and Risk Assessment for Use of Triclopyr TEA at Wetland Sites.

Exposure Scenario	AR (lb ae/A)	DFR (ug/cm ²)	TC (cm ² /hr)	Average Daily Dose ² (mg/kg/day)	MOE ³
Scouting (efficacy surveys)	6.0	13.5	1,500	0.054	93

1. Surrogate DFR = application rate (lb ae/A) x 20% available as dislodgeable residue x (1-0.10)^(days) x 4.54E8 ug/lb x 2.47E-8 A/cm². Ex. calc = 6.0 lb ae/A x 0.20 x 4.54E8 ug/lb x 2.47E-8 A/cm² = 13.5 ug/cm².

2. ADD = DFR (ug/cm²) x TC (cm²/hr) x 8 hrs/day x 0.001 mg/ug x 1/ BW x %dermal absorption; BW = 60 kg for adults; dermal absorption = 2%.

3. MOE = NOAEL/ ADD; short-term dermal NOAEL = 5 mg/kg bw/day. The LOC is for MOEs < 100 (occupational).

Attachment 5: Triclopyr International Residue Limit Status Sheet.

Table A19. Summary of US and International Tolerances and Maximum Residue Limits.				
<i>Residue Definition:</i>				
US	Canada	Mexico ¹	Codex	
US [40 CFR §180.417 (1) Tolerances for residues of the herbicide triclopyr per se, as a result of the application/use of butoxyethyl ester of triclopyr and triethylamine salt of triclopyr	3,5,6-trichloro-2-pyridyloxyacetic acid, including the metabolite 3,5,6-trichloro-2-pyridinol Milk: 3,5,6-trichloro-2-pyridyloxyacetic acid		None	
<i>Commodity</i>	<i>Tolerance (ppm) /Maximum Residue Limit (mg/kg)</i>			
	US	Canada	Mexico ¹	Codex
Egg	0.05			
Fish	3.0			
Grass, forage	700.0			
Grass, hay	200.0			
Milk	0.01	0.01		
Poultry, fat	0.1			
Poultry, meat	0.1			
Poultry, meat byproducts, except kidney	0.1			
Rice, grain	0.3			
Rice, straw	10.0			
Shellfish	3.5			
US [40 CFR §180.417 (2)	Canada	Mexico ¹	Codex ²	
Livestock: (2) Tolerances for the combined residues of the herbicide triclopyr ((3,5,6-trichloro-2-pyridinyl)oxy) acetic acid and its metabolite 3,5,6-trichloro-2-pyridinol (TCP), as a result of the application/use of butoxyethyl ester of triclopyr or the triethylamine salt of triclopyr	3,5,6-trichloro-2-pyridyloxyacetic acid, including the metabolite 3,5,6-trichloro-2-pyridinol Milk: 3,5,6-trichloro-2-pyridyloxyacetic acid		None	
<i>Commodity</i>	<i>Tolerance (ppm) /Maximum Residue Limit (mg/kg)</i>			
	US	Canada	Mexico ¹	Codex ²
Cattle, fat	0.05	0.1		
Cattle, kidney	0.5	0.5		
Cattle, liver	0.5	0.5		
Cattle, meat	0.05	0.1		
Cattle, meat byproducts, except kidney and liver	0.05	0.1		
Goat, fat	0.05	0.1		
Goat, kidney	0.5	0.5		
Goat, liver	0.5	0.5		
Goat, meat	0.05	0.1		
Goat, meat byproducts, except kidney and liver	0.05	0.1		
Hog, fat	0.05	0.1		
Hog, kidney	0.5	0.5		
Hog, liver	0.5	0.5		
Hog, meat	0.05	0.1		
Hog, meat byproducts, except kidney and liver	0.05	0.1		
Horse, fat	0.05	0.1		
Horse, kidney	0.5	0.5		
Horse, liver	0.5	0.5		
Horse, meat	0.05	0.1		
Horse, meat byproducts, except kidney and liver	0.05	0.1		
Sheep, fat	0.05	0.1		
Sheep, kidney	0.5	0.5		
Sheep, liver	0.5	0.5		
Sheep, meat	0.05	0.1		
Sheep, meat byproducts, except kidney and liver	0.05	0.1		
Completed: M. Negussie; 02/19/2014				

¹ Mexico adopts US tolerances and/or Codex MRLs for its export purposes.

